COMMISSION REGULATION (EC) No 437/2008

of 21 May 2008

amending Annexes VII, X and XI to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the requirements for the processing of milk and milk products defined as Category 3 material

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption [1], and in particular Article 32(1) thereof,

Whereas:

(1) Regulation (EC) No 1774/2002 lays down health rules concerning animal by-products not intended for human consumption. It provides that animal by-products that may be used as feed material have to be processed in accordance with the requirements laid down in that Regulation.

(2) Annex VII to Regulation (EC) No 1774/2002 sets out specific hygiene requirements for the processing and placing on the market of processed animal protein and other processed products that could be used as feed material. In particular, Chapter V of that Annex provides for specific requirements for the processing of milk, milk products and colostrum.

(3) In accordance with the first paragraph of Article 28 of Regulation (EC) No 1774/2002 the provisions applicable to the importation of products referred to in Annexes VII and VIII to that Regulation from non-member countries are not to be more favourable or less favourable than those applicable to the production and marketing of those products in the Community. Chapter V of Annex VII to that Regulation should therefore be amended, in order to introduce certain technical amendments, to harmonise the processing standards for milk and milk products and to clarify the import requirements applicable to them.

(4) Following the opinion of the European Food Safety Authority, adopted on 29 March 2006, related to the animal health risks of feeding animals with ready-to-use dairy products without further treatment [2], it is appropriate to amend the specific hygiene requirements for milk, milk-based products and colostrums. Account should also be taken of the methods for the inactivation of possible foot-and-mouth disease virus in milk described in the 1999 Report of the Scientific Committee on Animal Health and Animal Welfare on a Strategy for Emergency Vaccination against Foot-and-Mouth Disease [3] and of Appendix 3.6.2 of the Terrestrial Animal Health Code [4], 2005 edition, of the World Organisation for Animal Health (OIE).

(5) Taking account of the amended specific hygiene requirements in Chapter V of Annex VII to Regulation (EC) No 1774/2002, it is appropriate to replace the model health certificates in Chapters 2(A), 2(B) and 2(C) of Annex X to that Regulation by a single model certificate for the importation from third countries of milk and milk products not intended for human consumption.

(6) It is necessary to update the reference to the specific health certificate in Part I of Annex XI to Regulation (EC) No 1774/2002 setting out lists of third countries from which Member States may authorise imports of animal by-products not intended for human consumption.

(7) Annexes VII, X and XI to Regulation (EC) No 1774/2002 should therefore be amended accordingly.

[1] OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 399/2008 (OJ L 118, 6.5.2008, p. 12).

[2] http://www.efsa.europa.eu/en/science/ahaw/ahaw_opinions/1447.html

[3] http://ec.europa.eu/food/fs/sc/scah/out22_en.html

[4] http://www.oie.int/eng/normes/mcode/en_chapitre_3.6.2.htm

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes VII, X and XI to Regulation (EC) No 1774/2002 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall be applicable from 1 May 2008.

Consignments for which veterinary certificates were issued before 1 November 2008 in accordance with the models established by Regulation (EC) No 1774/2002 before its amendment by the present Regulation, shall be accepted for import into the Community until 1 February 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 May 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Regulation (EC) No 1774/2002 is amended as follows:

(1) In Annex VII, Chapter V is replaced by the following:

'CHAPTER V

Specific requirements for milk, milk products and colostrum

The following conditions apply in addition to the general conditions laid down in Chapter I.

A. *Processing standards*

1. Milk must be subjected to one of the following treatments:

1.1. sterilisation at an F_0 (*) value of three or more;

1.2. UHT (**) combined with one of the following:

(a) a subsequent physical treatment, by:

(i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

(ii) lowering the pH below 6 for at least 1 hour;

(b) the condition that the milk or milk product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin;

1.3. HTST (***) applied twice;

1.4. HTST (***) in combination with one of the following:

(a) a subsequent physical treatment, by:

(i) a drying process, combined in the case of milk intended for feeding with additional heating to 72 °C or more; or

(ii) lowering the pH below 6 for at least 1 hour;

(b) the condition that the milk or milk product has been produced at least 21 days before shipping and that during that period no case of foot-and-mouth disease has been detected in the Member State of origin.

2. Milk products must either be subjected to at least one of the treatments provided for in paragraph 1 or be produced from milk treated in accordance with paragraph 1.

3. Whey to be fed to animals of species susceptible to foot-and-mouth disease and produced from milk treated in accordance with paragraph 1 must be collected at least 16 hours after milk clotting and its pH must be recorded as below 6,0 before transport to animal holdings.

4. In addition to the requirements laid down in paragraphs 1, 2 and 3, milk and milk products must meet the following requirements:

4.1. after completion of the processing, every precaution must be taken to prevent contamination of the products;

4.2. the final product must be labelled so as to indicate that it contains Category 3 material and is not intended for human consumption, and

(a) packed in new containers; or

(b) transported in bulk in containers or other means of transport that before use were thoroughly cleansed and disinfected using a disinfectant approved for the purpose by the competent authority.

5. Raw milk and colostrum must be produced under conditions offering adequate guarantees as regards animal health. Such conditions may be established in accordance with the procedure referred to in Article 33(2).

B. *Importation*

1. Member States shall authorise imports of milk and milk products subject to compliance with the following conditions:

1.1. they come from third countries appearing on the list in Part I of Annex XI;

1.2. they come from a processing plant which appears on the list referred to in Article 29(4);

1.3. they are accompanied by a health certificate conforming to the model laid down in Chapter 2 of Annex X;

1.4. they have undergone at least one of the treatments provided for in paragraphs 1.1, 1.2, 1.3 and point (a) of paragraph 1.4 of Part A;

1.5. they comply with paragraphs 2 and 4, and, in the case of whey, paragraph 3 of Part A.

2. By way of derogation from paragraph 1.4, Member States shall authorise imports of milk and milk products from third countries so authorised in Column "A" of Annex I to Commission Decision 2004/438/EC (****) provided that the milk or milk products have undergone a single HTST treatment and have been produced:

(i) either at least 21 days before shipping and that during this period no case of foot-and-mouth disease has been detected in the exporting country; or

(ii) have been presented at an EU border inspection post at least 21 days after production and that during this period no case of foot-and-mouth disease has been detected in the exporting country.

3. Where a risk of introduction of an exotic disease or any other risk to animal health is identified, additional conditions for the protection of animal health may be established in accordance with the procedure referred to in Article 33(2).

(*) F_0 is the calculated killing effect on bacterial spores. An F_0 value of 3,00 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250 °F) in three minutes with instantaneous heating and chilling.

(**) UHT = Ultra High Temperature treatment at 132 °C for at least one second.

(***) HTST = High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or equivalent pasteurisation effect achieving a negative reaction to a phosphatase test.

(****) OJ L 154, 30.4.2004, p. 72, as corrected by OJ L 189, 27.5.2004, p. 57.'

(2) In Annex X, Chapters 2(A), 2(B) and 2(C) are replaced by the following:

'CHAPTER 2

Health certificate

For milk and milk products not intended for human consumption for dispatch to or for transit through the Community

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Tel. No		I.2. Certificate reference number	I.2.a
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel. No		I.6. Person responsible for the load in EU Name Address Postal code Tel. No	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Name Approval number Address		I.12. Place of destination Custom warehouse ☐ Name Approval number Address Postal code	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17. No(s) of CITES	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Identification of container/Seal number		I.24. Type of packaging	
I.25. Commodities certified for: Animal feedingstuff ☐ Further process ☐ Technical use ☐ Other ☐			
I.26. For transit through EU to third country ☐ third country ISO code		I.27. For import or admission into EU ☐	
I.28. Identification of the commodities Species Approval number of establishments Manufacturing plant Net weight Batch number			

COUNTRY **Milk and milk products not for human consumption**

Part II: Certification

II. Health information	II.a. Certificate reference number	II.b.

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002 (1), and certify that the milk (2) or the milk products (2) referred to in box I.28 comply with the following conditions:

1. they were produced and derived in ..... *(insert name of exporting country),* ..... *(insert name of region)* (3), which is listed in the Annex to Decision 2004/438/EC, and which has been free from foot-and-mouth disease (FMD) and rinderpest for 12 months immediately prior to export and has not practiced vaccination against rinderpest during that period;

2. they were produced from raw milk derived from animals which at the time of milking did not show clinical signs of any disease transmissible through milk to humans or animals, and which had been kept for at least 30 days prior to production on holdings that were not subject to official restrictions due to foot-and-mouth disease or rinderpest;

3. they are

(2) either [milk or milk products, excluding whey, that have undergone one of the treatments or combinations thereof described in point 4]

(2) *or* [they comprise entirely of whey with a pH below 6, which was collected not earlier than 16 hours after clotting from milk subjected to one of the treatments described in point 4]

4. they have been subject to one of the following treatments:

(2) either [High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds, or an equivalent pasteurisation achieving a negative reaction to a phosphatase test, in combination with:

(2) *either* a subsequent second High Temperature Short Time pasteurisation at 72 °C for at least 15 seconds or an equivalent pasteurisation which itself achieves a negative reaction to a phosphatase test]

(2) or a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72 °C or higher,]

(2) or a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6;]

(2) (4) *or* the condition that the milk/milk product has been produced at least 21 days before the shipping and in this period no cases of FMD has been detected in the exporting country;]

(2) (4) *or* the milk/milk product has been produced on ../../...., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a border inspection post of the European Union]

(2) *or* [sterilisation at a level of at least $F_0 3$]

(2) *or* [Ultra High Temperature treatment at 132 °C for at least one second in combination with:

(2) either a subsequent drying process that in the case of milk intended for feeding is combined with additional heating to 72 °C or higher,]

(2) *or* a subsequent process by which the pH is reduced and kept for at least one hour at a level below 6.]

(2) (4) *or* the condition that the milk/milk product has been produced at least 21 days before the shipping and in this period no cases of FMD has been detected in the exporting country;]

(2) (4) *or* the milk/milk product has been produced on ../../...., this date, in consideration of the foreseen voyage duration, being at least 21 days before the consignment is presented to a border inspection post of the European Union]

5. every precaution was taken to avoid contamination of the milk/milk product after processing;

6. the milk/milk product was packed:

(2) either [in new containers,]

(2) or [in vehicles or bulk containers disinfected prior to loading using a product approved by the competent authority,]

and the containers are marked so as to indicate the nature of the milk/milk product and bear labels indicating that the product is Category 3 material and not intended for human consumption.

COUNTRY **Milk and milk products not for human consumption**

Notes

Part I:

— Box reference I.6: Person responsible for the load in EU: this box is to be filled in only if it is a certificate for transit commodity.

— Box reference I.12: Place of destination: this box is to be filled in only if it is a certificate for transit commodity.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the BIP of entry into the EU.

— Box reference I.19: use the appropriate Harmonised System (HS) code of the World Customs Organisation: 23.09.10, 23.09.90, 35.01, 35.02 or 35.04.

— Box reference I.23: for bulk containers, the container number and the seal number (if applicable) should be included.

— Box reference I.26 and I.27: fill in according to whether it is a transit or an import certificate.

— Box reference I.28: "Manufacturing plant": provide the registration number of treatment or processing establishment.

Part II:

([1]) OJ L 273, 10.10.2002, p. 1.

([2]) Delete as appropriate.

([3]) For completion if the authorisation to import into the Community is restricted to certain regions of the third country concerned.

([4]) This condition applies only to third countries listed in column "A" of Annex I to Decision 2004/438/EC

— The signature and the seal must be in a different colour from that of the printing.

— Note for the importer: this certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:'

(3) In Annex XI, Part I is replaced by the following:

'PART I

List of third countries from which Member States may authorise imports of milk and milk products (health certificate Chapter 2)

Authorised third countries listed in Annex I to Decision 2004/438/EC.'